



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,431	05/22/2001	Shalaby Wahba Shalaby	00537-183002	4602

7590

01/28/2002

Brian R Morrill  
Biomeasure Incorporated  
27 Maple Street  
Milford, MA 01757

EXAMINER

BERMAN, ALYSIA

ART UNIT

PAPER NUMBER

1619

DATE MAILED: 01/28/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/762,431

**Applicant(s)**

SHALABY ET AL.

**Examiner**

Alysia Berman

**Art Unit**

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 11, 12 and 19, drawn to a polyester.

Group II, claim(s) 2, 3, 13 and 14, drawn to a conjugate comprising a polyester.

Group III, claim(s) 4, drawn to a microparticle comprising a polyester.

Group IV, claim(s) 5 and 6, drawn to a conjugate comprising a microparticle.

Group V, claim(s) 7 and 8, drawn to an acylated or alkylated polysaccharide.

Group VI, claim(s) 9 and 10, drawn to a conjugate comprising an acylated or alkylated polysaccharide.

Group VII, claim(s) 15 and 18, drawn to a pharmaceutical composition comprising a conjugate of Group II.

Group VIII, claim(s) 16, drawn to a pharmaceutical composition comprising a conjugate of Group IV.

Group IX, claim(s) 17, drawn to a pharmaceutical composition comprising a conjugate of Group VI.

Group X, claim(s) 20, drawn to a method of making a polyester.

Group XI, claim(s) 21, drawn to a method of making a phosphorylated-acylated cyclodextrin.

Group XII, claim(s) 22, drawn to a method of making a phosphorylated-alkylated cyclodextrin.

Group XIII, claim(s) 23, drawn to a method of making phosphorylated microparticles.

Art Unit: 1619

Group XIV, claim(s) 24 and 25, drawn to a method of making an acylated-phosphorylated polysaccharide.

Group XV, claim(s) 26, drawn to a phosphorylated-grafted-acylated cyclodextrin.

Group XVI, claim(s) 27, drawn to a method of making a phosphorylated-grafted-acylated cyclodextrin.

Group XVII, claim(s) 28, drawn to a conjugate comprising a phosphorylated-grafted-acylated cyclodextrin.

2. The inventions listed as Groups I-XII and XIV-XVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the corresponding technical feature common to inventions I-XII and XIV-XVII appears to be an absorbable polymer capable of forming a conjugate with a peptide and/or bioactive agent. This concept is already known from US 5,079,337, which discloses a phosphorylated dextran. Therefore, this technical feature is not a special technical feature that would distinguish over the prior art. The inventions cannot be considered to relate to a single general inventive concept. The invention of Group XIII does not require an absorbable polymer capable of forming a conjugate with a peptide and/or bioactive agent. Therefore, Group XIII does not share a technical feature with Groups I-XII and XIV-XVII. The inventions cannot be considered to relate to a single general inventive.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If Group I is elected, a monomer of claim 11 must be elected.

If any of Groups II, IV or VI is elected, a peptide of claim 3 must be elected.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

Art Unit: 1619

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

A monomer: claim 11.

A peptide: Claims 3, 6, 10 and 14.

The following claim(s) are generic: 1, 2, 5, 12 and 13.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: see the reasons above.

6. A telephone call was made to Y. Rocky Tsao on January 22, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

Art Unit: 1619


remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

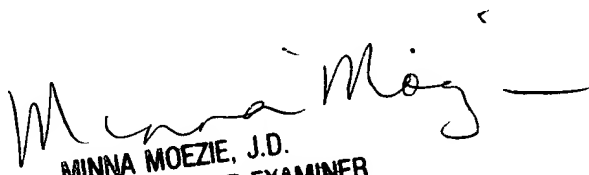
***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached Monday through Friday between 9:00 am and 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 or 703-872-9307 for after-final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.

  
Alysia Berman  
Patent Examiner  
January 23, 2002

  
MINNA MOEZIE, J.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600